

Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (previously presented) A pharmaceutical composition consisting essentially of fexofenadine or a pharmaceutical acceptable acid addition salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition.
2. (original) The composition according to Claim 1, wherein the salt of fexofenadine is fexofenadine hydrochloride.
3. (original) The composition according to Claim 1, wherein the amount of fexofenadine or pharmaceutical acceptable salt thereof is from about 1 wt. % to about 80 wt. %, based on the total weight of the pharmaceutical composition.
4. (original) The composition according to Claim 3, wherein the amount of fexofenadine or pharmaceutical acceptable salt thereof is from about 5 wt. % to about 50 wt. %, based on the total weight of the pharmaceutical composition.
5. (original) The composition according to Claim 4, wherein the amount of fexofenadine or pharmaceutical acceptable salt thereof is from about 20 wt. % to about 35 wt. %, based on the total weight of the pharmaceutical composition.
6. (original) The composition according to Claim 1, wherein the amount of fexofenadine or pharmaceutical acceptable salt thereof is from about 10 mg to about 200 mg.
7. (original) The composition according to Claim 6, wherein the amount of fexofenadine or pharmaceutical acceptable salt thereof is from about 30 mg to about 180 mg.
8. (original) The composition according to Claim 1, wherein the lactose is selected from the group consisting of lactose monohydrate, lactose anhydrous, α -lactose, β -lactose, and combinations thereof.
9. (original) The composition according to Claim 8, wherein the lactose is lactose monohydrate.
10. (original) The composition according to Claim 1, wherein the amount of lactose is from about 25 wt. % to about 65 wt. %, based on the total weight of the pharmaceutical composition.

11. (original) The composition according to Claim 10, wherein the amount of lactose is from about 50 wt. % to about 60 wt. %, based on the total weight of the pharmaceutical composition.

12. (original) The composition according to Claim 1, wherein the low-substituted hydroxypropyl cellulose when dried at 105 °C for 1 hour contains 5-16% of hydroxypropoxy groups.

13. (original) The composition according to Claim 12, wherein the low-substituted hydroxypropyl cellulose when dried at 105 °C for 1 hour contains 10-13% of hydroxypropoxy groups.

14. (original) The composition according to Claim 13, wherein the low-substituted hydroxypropyl cellulose is selected from the group consisting of: LH-11 having a hydroxypropoxy content of 11% and an average particle size of 50 microns; LH-21 having a hydroxypropoxy content of 11% and an average particle size of 40 microns; LH-31 having a hydroxypropoxy content of 11%, and an average particle size of 25 microns; LH-22 having a hydroxypropoxy content of 8%, and an average particle size of 40 microns; LH-32 having a hydroxypropoxy content of 8%, and an average particle size of 25 microns; LH-20 having a hydroxypropoxy content of 13%, and an average particle size of 40 microns; and LH-30 having a hydroxypropoxy content of 13%, and an average particle size of 25 microns.

15. (original) The composition according to Claim 14, wherein the low-substituted hydroxypropyl cellulose is LH-21 or LH-11.

16. (original) The composition according to Claim 1, wherein the low-substituted hydroxypropyl cellulose is present in an amount of from about 2 wt. % to about 25 wt. %.

17. (original) The composition according to Claim 16, wherein the low-substituted hydroxypropyl cellulose is present in an amount of from about 3 wt. % to about 15 wt. %.

18. (previously presented) A method of preparing a pharmaceutical composition consisting essentially of fexofenadine or a pharmaceutical acceptable acid addition salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition, said method comprising:

- (a) mixing fexofenadine, lactose, low-substituted hydroxypropyl cellulose, and optionally one or more excipients to form a premix;
- (b) adding a solvent and optionally a surfactant to the premix formed in Step (a) to form a wet granulation; and
- (c) drying the wet granulation to form dried granules;
- (d) optionally milling the dried granules; and

(e) mixing at least one excipient with the dried granules to form a pharmaceutical composition.

19. (previously presented) A method of preparing a pharmaceutical composition consisting essentially of fexofenadine or a pharmaceutical acceptable acid addition salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition, said method comprising:

- (a) mixing fexofenadine, lactose, low-substituted hydroxypropyl cellulose, and optionally one or more excipients to form a premix;
- (b) adding a solvent and optionally a surfactant to the premix formed in Step (a) to form a wet granulation; and
- (c) drying the wet granulation using a tray dryer to form dried granules;
- (d) optionally milling the dried granules using a low shear mill; and
- (e) mixing at least one excipient with the dried granules to form a pharmaceutical composition.

20. (original) The method according to Claim 19 wherein the low shear mill is a conical screen mill.